



The Science Behind Monoclonal Antibodies for COVID-19: Frequently Asked Questions

Q: What monoclonal antibody treatments are authorized for use?

A: The U.S. Food and Drug Administration (FDA) has granted emergency use authorizations (EUAs) for monoclonal antibodies to treat patients with mild to moderate COVID-19 and who are at high risk of developing severe symptoms. These treatments include:

- **REGEN-COV™ (Casirivimab and Imdevimab):** [Fact Sheet](#)¹ (revised version, March 18, 2021) and [EUA](#)² (reissued February 3, 2021 and February 25, 2021)
- **Bamlanivimab and Etesevimab:** [Fact Sheet](#)³ (revised version, March 18, 2021) and [EUA](#)⁴ (reissued February 25, 2021)
- **Bamlanivimab:** [Fact Sheet](#)⁵ (revised version, March 18, 2021) and [EUA](#)⁶ (reissued February 9, 2021 and March 2, 2021)

Note: Although bamlanivimab alone is currently authorized for emergency use, the U.S. Government, in coordination with Eli Lilly and Company, stopped distribution of bamlanivimab as a stand-alone treatment on March 24, 2021 due to the sustained increase in bamlanivimab-resistant variants of SARS-CoV-2 in the U.S.⁷ The NIH COVID-19 Treatment Guidelines Panel “recommends against the use of bamlanivimab monotherapy [...] If combination products are not available, the use of bamlanivimab monotherapy can be considered for people who meet the EUA criteria on a case-by-case basis.”⁸

Q: Which patients can be treated with the authorized monoclonal antibodies?

A: Monoclonal antibodies are authorized for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. Treatment must be given within 10 days of symptom onset, so it is critical to identify eligible patients at the point of diagnosis and inform them about the availability of monoclonal antibody treatment.⁹





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Q: What data supported the Emergency Use Authorization of the monoclonal antibodies?

A: Data from controlled clinical trials that showed that high-risk patients who received monoclonal antibodies had a decrease in the risk of progression to severe disease, hospitalization, or death compared to patients who received placebo was used in support of the EUA.^{1,3,5} The safety and efficacy of these therapies for use in the treatment of COVID-19 continue to be evaluated.

During certain types of emergencies¹⁰, the FDA may permit authorization based on the best available evidence to provide timely access to critical care when there are no adequate, approved, and available alternatives. This may include authorization of investigational products based on significantly less data than would be required for approval by the FDA.



Q: Are monoclonal antibodies effective against new SARS-CoV-2 variants?

A: The science on this question is evolving. Some circulating SARS-CoV-2 variants may be associated with resistance to monoclonal antibodies. The FDA recently updated the Antiviral Resistance information in Section 15 for each of the currently available treatments under emergency use. For further information, please reference:

- The FDA Center for Drug Evaluation and Research statement¹¹
- Information on CDC variant classifications and definitions¹²

Q: How do SARS-CoV-2 variants impact treatment decisions?

A: To guide treatment decisions, healthcare providers should:

- Review the Antiviral Resistance information in Section 15 of the authorized fact sheets for each monoclonal antibody therapy available under EUA¹³ for details on specific variants and resistance.
- Refer to the CDC website¹⁴, as well as information from state and local health authorities, for reports of viral variants in their region.



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For more information, visit
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